REMARKS

Claims 14-23 stand rejected. Claims 14-23 are amended herein. The claims have been amended to point out the invention more distinctly and to comply with the Office's suggestions and observations. Support for the amended claims is found throughout the specification but, as described in detail below, in particular on page 5, and in the Examples section. No new matter has been added and entry of the amendment is respectfully requested.

Claim Objections

The Applicants respectfully note the renumbering of the previously submitted claims from 19-27 to 15-23. The Applicants thank the Office for the correction of this oversight in the previously submitted claims.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 15-23 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention.

The Office states that the ranges recited in current claims 15, 21 and 23 are not found in, or supported by, the original specification. The Office asserts that ranges outside of those specifically disclosed are not fully supported. Although the Applicants respectfully disagree with the Office's assertion, in accordance with the Office's suggestion, Applicants have amended these claims to delete the word "about," while realizing that Applicants are entitled to a reasonable range of equivalents of the disclosed range.

The Office further states that the range of "0.2% to 2%" (reflected in current claim 15) does not find support for these particular endpoints from the disclosed ranges. The Office asserts that the claimed phospholipid range of "0.2% to 2%," is purportedly improper and not adequately supported. The Applicants respectfully direct the Office's attention to the Examples section. Example 1 provides three representative formulas of the claimed invention, each

formula provides the percent composition (w/w) of each component in the formula. In Formulas 1 and 2 the phospholipid concentration (i.e., Purified Lecithin) comprises 1.0% of the composition. In Formula 3, the phospholipid concentration comprises 0.2% of the composition. The 0.2% phospholipid concentration in Formula 3 is evident based on the inclusion of 10% of each of Formulas 1 and 2 in the total Formula 3 composition (i.e., a phospholipid concentration comprising: 1.0% of 10% of Formula 1, plus 1.0% of 10% of Formula 2 - equaling 0.2% (w/w) of the total Formula 3 composition). In addition, in Examples 2-4 the purified phospholipid concentration comprises 2.0% (w/w) of each of the Formulas described. Thus, the claimed range of 0.2% to 2% is fully supported by the Examples an in accordance with the Court of Customs and Patent Appeals decision *In re Wertheim*, 191 USPQ 90 (CCPA 1976) (attached hereto as Exhibit B) and MPEP § 2163.05 (range limitations). As provided in the MPEP in its description of the *In re Wertheim* decision,

> the ranges described in the original specification included a range of "25% - 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement.

MPEP § 2163.05.

Accordingly, Applicants respectfully request that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

The rejections under 35 U.S.C. § 112, second paragraph

Claims 15-23 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Office has indicated that the phrase "bilayer forming lipid," in current claim 15, should be amended to "bilayer-forming lipid" to more clearly define the invention. Accordingly, the amended claim 15 includes this suggested phrase. It is believed that the present amendments

to claim 15 merely clarify certain aspects of the present invention and, as these amendments are not made for reasons related to patentability, they do not narrow the intended scope of the claims.

The Office has indicated that current claims 15 and 18-20 recite improper Markush-type language. Accordingly, claims 15 and 18-20 are amended to conform with the Office's suggestion. It is believed that the present amendments to claims 15 and 18-20 merely clarify certain aspects of the present invention and, as these amendments are not made for reasons related to patentability, they do not narrow the intended scope of the claims.

Accordingly, the Applicants assert that the language of claims 15-23 is clear and meets the requirements of 35 U.S.C. § 112, second paragraph. It is believed that the presently described amendments to claims 15 and 18-20 merely clarify certain aspects of the present invention and, as these amendments are not made for reasons related to patentability, they do not narrow the intended scope of the claims.

The Rejections under 25 U.S.C. § 102(e)

The Examiner has rejected current claims 15-23 under 35 U.S.C. § 102(e) as allegedly anticipated by Mehansho et al. (U.S. Patent No. 5,707,670). In this rejection the Office has stated that "the claims simply state that the preparations are 'useful as an infant formula,' and are not limited to an 'infant formula' *per se*. In this context the Office has questioned why Mehansho's chocolate milk formulations would not serve the same purpose. The Office has further stated that the ratio of divalent mineral salt to edible carrier (i.e., liposome according to the Office) in Mehansho can vary between "about 1:1 to about 1:500" and that this range reads on the range disclosed in the present specification, i.e., "50%."

The claims as currently provided are directed to liposomal-based preparations useful as infant formula preparations. The currently claimed preparations are comprised of between 0.2% to 2% (w/w) phospholipids. The preparation of the presently claimed liposomal-based infant formulas allows said formulas to more closely resemble natural human milk (*see* specification at

page 4, lines 24-25). Further, the inclusion of a phospholipid component in the claimed formulas at the same concentration as that found in human milk has the added benefit of enhancing the bioavailability of encapsulated nutrients. Previous infant formulas have not included liposomes and have failed to produce a close substitute to human milk.

Respectfully, there is no indication in Mehansho of formulations comprising the same phospholipid concentration as currently claimed. Therefore, for argument purposes, even if Mehansho taught the range of divalent mineral salt to edible carrier as asserted by the office (i.e., from about 1:1 to about 1:500; or otherwise stated as having an edible carrier percentage between 50% to over 99.9% of the resulting composition), this range does not read on or inherently disclose the phospholipid concentration range as currently claimed (i.e., between 0.2% to 2% (w/w) phospholipids). In addition, Mehansho does not disclose preparations which would closely resemble the composition of human milk or the claimed compositions, and thus provide the added benefit of increased bioavailability of the present formulations.

Based on the foregoing, the Applicants respectfully assert that Mehansho is inapplicable to the new claims because it does not disclose every element of the claims neither expressly nor inherently. See MPEP § 2131.

For the foregoing reasons, it is believed that claims 15-23 are clearly patentable over the prior art cited.

The current claims

While not relevant to any outstanding rejection or the patentability of the pending claims, the Applicants would like to provide a point of clarification. The Office appears to have indicated that the claimed preparations are comprised of a "simple two-component liposome" (see Paper No. 11, page 3). Although two components are specifically delineated, the claims are couched in "comprising" language. Moreover, the use of the term "an" when referring to "an active ingredient" in the claims should not present a limitation to one ingredient. Rather, as provided in the claims, "one or more" active ingredients are intended (see e.g., the Formulas

provided throughout the specification). This position is fully supported by the claim language, the specification as filed, the Applicant's position throughout, and current authority on the subject.[1] Thus, the pending claims encompass multiple component preparations useful as infant formulas.

[1] See e.g., *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 52 USPQ2d 1109, 1112 (Fed. Cir. 1999) ("While the article 'a' or 'an' may suggest 'one,' our cases emphasize that 'a' or 'an' can mean 'one' or 'more than one,' depending on the context in which the article is used."); *Abtox, Inc. v. Exitron Corp.*, 43 USPQ2d 1545, 1548 (Fed. Cir. 1997) ("[T]he article 'a' suggests a single chamber. However, patent claim parlance also recognizes that an article can carry the meaning of 'one or more,' for example in a claim using the transitional phrase 'comprising.'").

CONCLUSION

Applicants understand that amendments after final are discretionary; however, entry of the amendment and passing the application to allowance (as there appears to be no remaining issues) appears more straightforward and more efficient than resolving these matters on appeal. Accordingly, the consideration of the Office of these amendments is respectfully requested.

If matters remain that can be resolved by phone, a phone call to the undersigned would be appreciated.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. 270142000300.

Respectfully submitted,

Dated: May 20, 2003

By: 

David L. Devernoe
Registration No. 50,128

Morrison & Foerster LLP
3811 Valley Centre Drive
Suite 500
San Diego, California 92130-2332
Telephone: (858) 720-7943
Facsimile: (858) 720-5125

EXHIBIT A: MARKED-UP VERSION OF AMENDMENTS TO THE CLAIMS.

In the Claims:

Please replace claims 15, 17-21 and 23 with the following claims 15, 17-21 and 23.

15. (Amended) A [liposome] liposomal-based preparation useful as an infant formula, comprising a natural bilayer-forming lipid component and an active ingredient component,

wherein the lipid component consists of a phospholipid concentration of [about 0.1% to about 50%] between 0.2% to 2.0% (w/w) of the total liposome composition, and

wherein the active ingredient component [is] comprises one or more components selected from the group consisting of micronutrients, proteins, immunoglobulins, vitamins and minerals.

17. (Amended) The liposome preparation of claim 15, wherein the phospholipid concentration is between [0.2] 1% to 2% of the total liposome composition.

18. (Amended) The liposome preparation of claim 15, wherein the lipid component [comprises] is selected from the group consisting of glycerolphospholipids, [or] sphingophospholipids, [or] and mixtures thereof.

19. (Amended) The liposome preparation of claim 18, wherein the lipid component is selected from the group consisting of glyceroglycolipids, [and] sphinogoglycolipids, [or] and mixtures thereof.

20. (Amended) The liposome preparation of claim 19, further comprising a stabilizer, wherein the stabilizer is selected from the group consisting of cholesterol, stigmasterol, [and] carrageenan, [or] and mixtures thereof.

21. (Amended) The liposome preparation of claim 20, wherein the concentration of the stabilizer comprises [about] 0.05% to [about] 30% w/w of the liposome preparation.

23. (Amended) The liposome preparation of claim 15, wherein the liposome preparation includes liposomes having a size range between [about] 50nm and [about] 100nm.